K102063

OCT 11 2011

510(k) Summary

7-Oct-11

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Proprietary or Trade Name: Health-e-Connect System

Common/Usual Name: Blood Glucose Meter

Classification Name: System, Test, Blood Glucose OTC
NBW – 862.1345, Class – 2
Calculator/Data Processing Module for Clinical Use
JQP – 862.2100, Class – 1

Predicate Device: K062770
Copilot Health Management System
Abbott Diabetes Care Inc.

K090801
Electronic House Call System
Express MD Solutions, LLC

Device Description:
The ALRT Health-e-Connect System (HeC) is an internet based blood glucose monitoring system that allows healthcare providers and patients the opportunity to review, analyze and evaluate the efficacy of a diabetes management program. It is expected that this functionality will significantly improve HbA1C levels in patients with diabetes.

Note there are no physical, electrical, biocompatibility or sterility specifications for this device as it is software only. It performs two functions: it is a data management tool and a communication platform.

The Health-e-Connect System is comprised of a home based application, legally marketed peripherals (blood glucose meters) and a server.

The home based application software collects data from blood glucose meters and transmits the data over the home's existing internet connection where it is uploaded to the Health-e-Connect System's web-based servers.

The server is a web-based application that collects, range checks, stores and displays historical patient blood sugar levels. It also allows patients, healthcare providers, patient relatives and other healthcare providers involved in the case to send messages to each other and share patient information. This communication is retrospective and not a real- time alert or alarm. The Health-e-Connect System is a tool to monitor patients remotely and motivate them through notifications.

Intended Use
The Health-e-Connect System is a remote, retrospective tool to supplement a patients' care. The Health-e-Connect System is intended to be a simple "store and forward" communications platform that allows clinicians and authorized users to access a patients' information for review and feedback. The Health-e-Connect System is a tool to monitor patients remotely and motivate them through notifications. The Health-e-Connect System is not intended to replace existing treatments or consultations, nor is it to be used as a substitute for a qualified healthcare provider's judgment or treatment plan. The Health-e-Connect System is not intended to act as an emergency response system.

Indications for Use:
The Health-e-Connect System is intended for use in the home and clinical settings by people with diabetes and healthcare providers as an aid in the review, analysis and evaluation of historical glucose test results and associated usage data in support of an effective diabetes management program.

Patient Population:
Patient with diabetes

Environment of Use:
Home and clinical environments

Contraindications:
None

Technology:
The Health-e-Connect System is a software based data processing system. The device operates on personal computers and across the internet via encrypted communications.

Materials:
No patient contacting materials

Performance Testing
The HeC was tested with 1 different meter models. The following tests were performed as part of the verification.

Bench Testing

Test: **View Glucometer summary of a user**
Procedure: Correct Glucometer summary (checked against paper copy & calculations)

Test: **Glucometer usage uploaded into the HEC**
Procedure: Take a blood test and check blood-sugar value on glucometer. Connect glucometer to HeC Desktop Programmer and upload. Check HeC recorded value.

Test: **Patient information and import data are not associated correctly**
Procedure: Performed many uploads of the glucometer. For each upload, a log is created, manually checked the log for the uploads.

Test: **Glucose analysis is flawed and the results are not correct in the HeC-RCS**
Procedure: The code which analyzes the glucometers values is checked thoroughly against other algorithms calculating the same statistics to verify accuracy.

Glucose meter test summary

Manufacturer	Model	Test 1	Test 2	Comment
Bayer	Breez™	pass	Pass	Verified
	Contour™	pass	Pass	Verified
Abbott	Freestyle Freedom™	pass	Pass	Verified
	Freestyle Freedom Lite™	pass	Pass	Verified
	Freestyle Lite™	pass	Pass	Verified
	Precision Xtra™	pass	Pass	Verified
Roche	ACCU-CHEK™ Aviva	pass	Pass	Verified
	ACCU-CHEK™ Compact Plus	pass	Pass	Verified
Lifescan	OneTouch™ Ultra 2	pass	Pass	Verified
	OneTouch™ Ultra Mini	pass	Pass	Verified

Test 1: connection/communication between glucose meter and ALRT HeC System using manufacturers' data cable and various rated operating systems.

Test 2: verification of data transfer- accuracy and completeness of data, all required fields, sent to correct account.

Non-clinical Testing:

A series of Usability / Human Factor studies were performed with lay users and healthcare providers. Overall 22 lay users and 2 HCP were involved. The Human Factor

Study (HFS) was intended to evaluate the usability of the Health-e-Connect (HeC) System, including aspects of user friendliness, design and so forth. The study was conducted by surveying users of the system that were able to evaluate such aspects as manual data entry, electronic data uploads, reports, messaging and other functions. Participants included patients with diabetes and caregivers.

Clinical Testing:
Clinical testing was not performed to support this submission as the HeC is a data collection device only.

Conclusions:

Bench testing: All meters passed the outlined tests.

Usability / Human Factors Study: Results of this HFS indicate that the HeC System is user friendly, is fast and easy to use and that users were able to successfully perform the various functions within the system.

Comparison to Predicates:

Indications –
The Health-e-Connect System has same indications for use at the predicate K062770.

The Health-e-Connect System is intended for use in the home and clinical settings by people with diabetes and healthcare providers as an aid in the review, analysis and evaluation of historical glucose test results and associated usage data in support of an effective diabetes management program.

Technology –
The HeC has the same technology, software and internet, as the predicates K062770 and K090801.

Materials –
The HeC and the predicate have no patient contact materials

Environment of Use –
The environments of use, home and clinical, are the same as the predicates K062770 and K090801.

Patient Population –
Patients with diabetes is the same patient populations as the predicate devices K062770 and K090801

Attribute	Express MD Solutions, LLC Electronic House Call System 510(k) K090801	Abbott Diabetes Care CoPilot 510(k) K062770	ALR Technologies Health-e-Connect 510(k) unknown	Discussion of Differences
Indications for Use	The Electronic House Call System (Electronic House Call Device + Electronic House Call Application + Electronic House Call Website) is a remote, retrospective monitoring tool for supplement in a patients' care. The Electronic House Call Device together with the Electronic House Call Application is intended to be a simple "store and forward" communications platform that allows clinicians and privileged users to access a patients' information for review through the Electronic House Call Website. The Electronic House Call Device is a tool to monitor patients' remotely and motivate them through education and reminders. The Electronic House Call System allows patients to measure vital signs without assistance from their healthcare provider. The Electronic House Call System is not intended to replace existing treatments or consultations, nor is it to be used as a substitute for a qualified healthcare professional's judgment/treatment plan. The Electronic House Call System is also not intended to act as an emergency response system.	The CoPilot Health Management System is intended for use in the home and clinical settings by people with diabetes and healthcare professionals as an aid in the review, analysis and evaluation of historical glucose test results in support of an effective diabetes management program.	The Health-e-Connect System is intended for use in the home and clinical settings by people with diabetes and healthcare providers as an aid in the review, analysis and evaluation of historical glucose test results and associated usage data in support of an effective diabetes management program.	Equivalent to K090801 and K062770 Connects to blood glucose meters
Environments of use	Home and clinical environments (not explicitly stated)	Home and clinical environments (not explicitly stated)	Home and clinical environments	Same
Data Sources	Various legally marketed devices	Keyboard entry and blood glucose meters	Keyboard entry and blood glucose meters	Same as K062770
Connectivity	Various devices to computer	BG meters to computer	BG meters to computer	Health-e-Connect provides a less cumbersome, more reliable means of communication
	Telephone line or other identified method (existing high-speed connection in patient's home)	Computer to health care provider via printing faxing or emailing	Computer to computer via internet	Health-e-Connect provides a less cumbersome, more reliable means of communication
Output	Email to clinician	Various representations of historical blood glucose values and statistics.	Various representations of historical blood glucose values and statistics. Email or SMS message to patient	Similar to K062770
Prescriptive	Yes	No	No	Same as K062770

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ALR Technologies
c/o Promedic Inc.
Paul Dryden
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: k102063
Trade name: Health-e-Connect System

OCT 11 2011

Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: September 22, 2011
Received: September 23, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102063

Device Name: Health-e-Connect System

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Prescription Use	**or**	**Over-the-counter use XX**
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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